K130114

510(K) SUMMARY

APR 1 6 2013

The following information is provided as required by 21 CFR § 807.87 for the Painmaster MCT Patch 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Newmark Inc.
131 Quarry Village Rd.
Cheshire, CT 06410

Manufacturer Newmark Inc.
182 Sandbank Road
Cheshire, CT 06410
Registration Number: 1226514

Contact: M Squared Associates, Inc.
Cherita James
901 King Street, Suite 101
Alexandria, VA 22314
Ph. 703-562-9800 Ext 257
Fax. 703-562-9797

Date of Submission: January 15, 2013

Proprietary Name: Painmaster MCT Patch

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Regulation Number: 21 CFR 882.5890

Regulatory Class: II

Product Code: NUH

Predicate Device(s): Painmaster MCT Patch (K090042), Prizm Medical 5000Z (K033122)

Device Description: The Painmaster MCT Patch operates in a single non-programmable microcurrent mode, delivering a pulsed monophasic waveform that provides electrical stimulation to the body to relieve pain. The Painmaster MCT Patch consists of two electrodes mounted on adhesive material connected by a small-diameter wire. One electrode contains the control unit that includes a small circuit board, a battery, and an LED light.

Intended Use: The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Technological Characteristics
The technological characteristics of the Painmaster MCT Patch are identical to the device cleared under K090042.

Performance Testing
Additional performance testing was not required to determine the substantial equivalence of this device for OTC use because the device is the same as the device previously cleared via 510(k) #K090442.

Usability Study
A usability study was conducted in support of the previous submission and demonstrated that users could correctly identify themselves as candidates for treatment, and could properly assemble and apply the device according to the instructions for use. The revised labeling is comparable to the previous labeling in presentation of device selection and application.

No additional usability evaluation or clinical data was required in support of this submission.

Conclusion
The Painmaster MCT Patch is substantially equivalent to legally marketed devices because it has the same technological characteristics and the same intended use as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2013

Newmark, Inc.
C/O Ms. Cherita James
M Squared Associates, Inc.
901 King Street, Ste 101
Alexandria, Virginia 22314

Re: K130114
Trade/Device Name: Painmaster MCT Patch
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: January 15, 2013
Received: January 16, 2013

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130114

Device Name: Newmark Painmaster MCT Patch

Indications For Use:

The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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